

Cumulative CBER Breakthrough Therapy Approvals

Data as of December 31, 2015

Application Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date	Use
BLA 125546	ORIGINAL-1	BEXSERO	Meningococcal Group B Vaccine	Novartis Vaccines and Diagnostics, Inc.	23-Jan-15	Active immunization to prevent invasive meningococcal disease caused by N. meningitidis serogroup B in individuals 10 through 25 years of age.
BLA 125549	ORIGINAL-1	TRUMENBA	Meningococcal Group B Vaccine	Wyeth Pharmaceuticals, Inc.	29-Oct-2014	Active immunization to prevent invasive meningococcal disease caused by N. meningitidis serogroup B in individuals 10 through 25 years of age.

* Breakthrough Therapy designation was enacted in the Food and Drug Administration Safety and Innovation Act on July 9, 2012.